IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC. and EMORY UNIVERSITY, Plaintiffs, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC., Defendants.	C.A. No.1:18-cv-00765-JFB-SRF

ANSWER TO COMPLAINT OF MAY 18, 2018

Defendants, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd., (collectively for purposes of this answer, "AUROBINDO" or "DEFENDANTS") answers the Complaint of May 18, 2018 filed by Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs") as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

ANSWER: Paragraph 1 contains conclusions of law to which no answer is required. To the extent an answer is required, Aurobindo admits that Plaintiffs purport to bring this action under the patent law of the United States. To the extent any other allegations remain in Paragraph 1, Aurobindo denies the same.

The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

ANSWER: On information and belief, Aurobindo admits that Gilead is a corporation organized and existing under the laws of the State of Delaware with a place of business at 333 Lakeside Drive, Foster City, California 94404. To the extent any remaining allegations of Paragraph 2, as Aurobindo lacks knowledge or information sufficient to form a belief as to such allegations, Aurobindo denies the same.

3. Emory is a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

ANSWER: On information and belief, Aurobindo admits that Emory is a corporation organized and existing under the laws of the State of Georgia and has an office at 2011 Dowman Drive, Atlanta, Georgia 30322. To the extent of any remaining allegations of Paragraph 3, as Aurobindo lacks knowledge or information sufficient to form a belief as to such allegations, Aurobindo denies the same.

4. On information and belief, defendant Aurobindo Pharma Ltd. ("Aurobindo Ltd") is an Indian corporation with a principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

ANSWER: Aurobindo Pharma Ltd. ("Aurobindo Ltd") admits it is an Indian corporation with a place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad 500038, India.

5. On information and belief, defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a Delaware corporation with a principal place of business at 279 Princeton-Hightstown Rd, East Windsor, New Jersey 08520-1401.

ANSWER: Admitted.

6. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd, and is controlled and/or dominated by Aurobindo Ltd.

ANSWER: Paragraph 6 contains conclusions of law to which no answer is required. To the extent an answer is required, Aurobindo admits that Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd., and denies any remaining allegations of Paragraph 6.

7. On information and belief, Aurobindo Ltd and Aurobindo USA regularly transact business within Delaware, including but not limited to, through Aurobindo Ltd's direction of the operations and management of Aurobindo USA, as well as shipping generic drugs to Aurobindo USA from locations outside the United States for marketing, sale, and distribution by Aurobindo USA within the United States generally, and Delaware specifically.

ANSWER: Paragraph 7 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo states that it will not contest personal jurisdiction in the District of Delaware for the limited purpose of this action only. To the extent of any remaining allegations, Aurobindo denies the same.

Jurisdiction and Venue

8. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21 of the United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 8 contains conclusions of law for which no response is required. To the extent that a response is required, Aurobindo admits that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Aurobindo Ltd.

ANSWER: Paragraph 9 contains conclusions of law to which no an answer is required. To the extent an answer is required, Aurobindo does not admit personal jurisdiction in this judicial

district is proper, however, Aurobindo waives its objection to personal jurisdiction for purposes of this action only, and denies the remaining allegations of Paragraph 9.

10. On information and belief, this Court has jurisdiction over Aurobindo Ltd because Aurobindo USA is a Delaware corporation and is the subsidiary and agent of Aurobindo Ltd. On information and belief, Aurobindo USA is acting as the agent of Aurobindo Ltd with respect to Abbreviated New Drug Application ("ANDA") No. 21-1640. On information and belief, Aurobindo Ltd and Aurobindo USA are working in concert for purposes of developing, formulating, manufacturing, marketing, selling, and importing drug products throughout the United States, including Delaware, and Delaware would be a destination of Aurobindo's ANDA products.

ANSWER: Paragraph 10 sets forth legal conclusions based on alleged activities to which no response is required. To the extent a response is required, Aurobindo, while not admitting personal jurisdiction is proper, states that it will not contest personal jurisdiction in the District of Delaware for the limited purposes of this action only, and denies any remaining allegations of Paragraph 10.

11. In the alternative, this Court has jurisdiction over Aurobindo Ltd because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Aurobindo Ltd because, *inter alia,* this action arises from actions of Aurobindo Ltd directed toward Delaware, and because Aurobindo Ltd has purposely availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Aurobindo Ltd regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. On information and belief, Aurobindo Ltd derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

ANSWER: Paragraph 11 sets forth legal conclusions based on alleged activities to which no response is required. Although Aurobindo do not admit the personal jurisdiction is proper, it will not contest personal jurisdiction in the District of Delaware for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 11.

12. On information and belief, this Court has personal jurisdiction over Aurobindo USA.

ANSWER: Paragraph 12 sets forth legal conclusions based on alleged activities to which no response is required. Although Aurobindo do not admit the personal jurisdiction is proper, it will not contest personal jurisdiction in the District of Delaware for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 12.

13. On information and belief, Aurobindo USA is a corporation registered with the Delaware Department of State, Division of Corporations, under file number 3769913.

ANSWER: Admitted.

14. On information and belief, Aurobindo USA maintains a registered agent for service of process in Delaware, the Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

ANSWER: Admitted.

15. On information and belief, Aurobindo USA is a generic pharmaceutical company in the business of marketing and distributing generic drug products, and derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in Delaware.

ANSWER: Paragraph 15 contains conclusions of law to which no answer is required. Although Aurobindo does not admit that personal jurisdiction in this judicial district is proper, Aurobindo waives it objection to personal jurisdiction for purposes of this action only. Aurobino denies the remaining allegations of Paragraph 15 as stated.

16. On information and belief, Aurobindo USA, itself or through one of its wholly-owned subsidiaries, manufactures pharmaceutical drug products that are sold and used throughout the United States, including in Delaware.

ANSWER: Paragraph 16 contains conclusions of law to which no answer is required. Although Aurobindo does not admit that personal jurisdiction in this judicial district is proper,

Aurobindo waives it objection to personal jurisdiction for purposes of this action only. Aurobino denies the remaining allegations of Paragraph 16 as stated

17. On information and belief, residents of Delaware purchase pharmaceutical drug products marketed by Aurobindo USA in Delaware.

ANSWER: Admitted.

18. On information and belief, Aurobindo USA holds a Delaware pharmacy wholesale license (No. A4-0001270) and a Delaware controlled substances distributor/manufacturer license (No. DM-0006550).

ANSWER: Paragraph 18 contains conclusions of law to which no answer is required. To the extent required Aurobindo admits it has obtained a Delaware Pharmacy Wholesale License and a Delaware Controlled Substances Distributor/Manufacturer License.

19. On information and belief, Aurobindo USA's submission of ANDA No. 21-1640, discussed below, indicates Aurobindo's intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with Gilead's Truvada® product, which is currently being sold throughout the United States, including in Delaware. On information and belief, Aurobindo will sell tablets containing 100 mg/150 mg, 133 mg/200 mg, and 167 mg/250 mg of emtricitabine/tenofovir disoproxil fumarate, respectively, for the use for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, throughout the United States, including in Delaware.

ANSWER: Aurobindo admits the strengths and combination products recited are covered by its referenced ANDA. No. 21-1640. It also admits that its ANDA seeks to engage in the manufacture, use, sale and/or importation of such products. As far as Aurobindo's ultimate intention in respect of these products, many factors will come into play in whether Aurobindo actually manufactures, uses, sells and/or imports such products, and if sales occur where such sales will be made, and thus it denies the remainder of the allegations.

20. On information and belief, Aurobindo has availed itself of this Court's jurisdiction by filing counterclaims in this District, and has previously been sued in this district and has not challenged personal jurisdiction. See, e.g., Amgen Inc. v. Aurobindo

Pharma Ltd. et al., C.A. No. 16-853-MSG (D. Del.); Allergan Sales LLC v. Aurobindo Pharma Ltd. et al., C.A. No. 15-1032 (D. Del.); Reckitt Benckiser LLC v. Aurobindo Pharma Ltd. et al., C.A. No. 14-1203 (D. Del.).

ANSWER: Paragraph 20 contains conclusions of law to which no answer is required. Although Aurobindo does not admit personal jurisdiction in this judicial district is proper, Aurobindo waives it object to personal jurisdiction for purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 20.

21. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b). Specifically, venue is proper in Delaware because Aurobindo USA is incorporated in Delaware.

ANSWER: Paragraph 21 contains conclusions of law to which no answer is required. Although Aurobindo does not admit that venue in this Court is proper, Aurobindo waives its objection to venue for purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 21.

Background

22. Gilead is the holder of New Drug Application ("NDA") No. 21-752 which relates to tablets containing emtricitabine and tenofovir disoproxil fumarate. On August 2, 2004, the United States Food and Drug Administration ("FDA") approved the use of the tablets containing 200mg of emtricitabine and 300mg of tenofovir disoproxil fumarate for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Truvada®. On March 10, 2016, the FDA approved Truvada® in the following emtricitabine/tenofovir disoproxil fumarate dosage strengths for the treatment of HIV-1 infection in pediatric patients: 167mg/250mg, 133mg/200mg, and 100mg/150mg ("low dosage strengths").

ANSWER: Admitted.

23. United States Patent No. 6,642,245 ("the '245 Patent," copy attached as Exhibit A), entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2003. The '245 Patent claims, *inter alia,* methods for treating HIV infection in humans with emtricitabine (one of the active

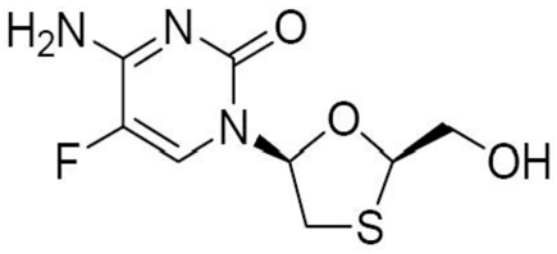
ingredients in Truvada®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Truvada®.

ANSWER: Aurobindo admits that the '245 Patent is entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane," and the face of the patent states it has an issue date of November 4, 2003. It also admits that it is listed in the FDA Orange Book. Aurobindo denies that the '245 Patent was dully and lawfully issued, and references the patent claims for what is or is not covered.

24. United States Patent No. 6,703,396 ("the '396 Patent," copy attached as Exhibit B), entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers," was duly and legally issued by the United States Patent and Trademark Office on March 9, 2004. The '396 Patent claims, *inter alia,* emtricitabine (one of the active ingredients in Truvada®), and is listed in the FDA Orange Book for Truvada®.

ANSWER: Aurobindo admits that the '396 Patent is entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers," and the face of the patent states it has an issue date of March 9,2004. It also admits that it is listed in the FDA Orange Book. Aurobindo denies that the '396 Patent was dully and lawfully issued, and references the patent claims for what is or is not covered.

25. Emtricitabine is a compound that has a molecular formula of $C_8H_{10}FN_3O_3S$, and which has the following chemical structure:



ANSWER: Admitted.

26. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Emtriva® label is "5-fluoro-1-[(2R,55)-2-(hydroxymethyl)- 1,3-oxathiolan-5-yl]cytosine." Two chemical names recited for emtricitabine in the '245 Patent are "(-)-P-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane" and "P-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane" Two chemical names recited for emtricitabine in the '396 Patent are "(-)-cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one" and "(-)-enantiomer of cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one"

ANSWER: Paragraph 26 contains conclusions of law to which no answer is required. Aurobindo agrees Emtricitabine can be referred to by any of several chemical names which can be found on Chemical Abstract, ChemSpider and the likes, but denies other allegations of the Paragraph 26, particularly as they conflate all such chemical names.

27. The named inventors on the '245 and '396 Patents are Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi.

ANSWER: Admitted.

28. Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi assigned the '245 and '396 Patents to Emory.

ANSWER: Aurobindo agrees that USPTO assignment records appear to indicate that Liotta, Schinazi and Choi assigned their rights to the '245 and '396 Patent to Emory. However, as Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 28, and therefore denies the same.

29. Pursuant to an agreement entered into between Gilead and Emory, Gilead has substantial rights in the '245 and '396 Patents, including, but not limited to, rights associated with being a licensee of the '245 and '396 Patents, and the right to sue for infringement of the '245 and '396 Patents.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29, and therefore denies the same.

COUNT 1
Infringement of U.S. Patent No. 6,642,245

30. Plaintiffs repeat and reallege paragraphs 1-29 above as if set forth herein.

ANSWER: Aurobindo repeat, reiterate and re-allege their responses to paragraph 1 through and including 29 of the Complaint with the same force and effect as if hereinafter set forth at length.

31. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate (i.e., 100mg/150mg, 133mg/200mg, and 167mg/250mg) for the purpose of treating HIV infection.

ANSWER: Admitted.

32. By letter dated April 5, 2018 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "April 5, 2018 Notice Letter"), Aurobindo USA notified Plaintiffs that it had submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the '245 Patent.[1] This complaint has been filed within 45 days of Plaintiffs' receipt of the April 5, 2018 Notice Letter.

ANSWER: Aurobindo admits that by letter dated April 5, 2018, Aurobindo USA notified Plaintiffs that it had submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the '245 Patent. As Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegation of Paragraph 32 as to the actual receipt date by Plaintiff' of the Notice Letter, it therefore denies the remaining allegations.

[1] Plaintiff note: Aurobindo amended its Paragraph IV Notice Letter on May 9, 2018.

33. In its April 5, 2018 Notice Letter, Aurobindo USA notified Plaintiffs that, as a part of ANDA No. 21-1640, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '245 Patent. Paragraph IV requires, *inter alia,* certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '245 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted. . . . ."

ANSWER: Paragraph 33 contains conclusions of law to which no answer is required. To the extent an answer is required, such allegations are admitted.

34. Aurobindo USA alleged in its amended May 9, 2018 Notice Letter that claims 1-8 and 15 of the '245 Patent are invalid and that claims 4, 5, and 9-22 would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 21-1640.

ANSWER: Plaintiffs are directed to the Notice Letter of May 9, 2018 as the best evidence of what was alleged by Aurobindo.

35. The May 9, 2018 Notice Letter does not allege non-infringement of claims 1-3 and 6-8 of the '245 Patent.

ANSWER: Plaintiffs are directed to the Notice Letter of May 9, 2018 as the best evidence of what was alleged by Aurobindo.

36. By filing ANDA 21-1640 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate before the '245 Patent's expiration, Aurobindo has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

37. Aurobindo's submission of ANDA No. 21-1640 and service of the April 5, 2018 Notice Letter indicates a refusal to change its current course of action.

ANSWER: Denied.

38. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil

fumarate for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, will infringe one or more claims of the '245 Patent.

ANSWER: Denied.

39. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 1 of the '245 Patent. Claim 1 recites a "method for treating HIV infection in humans comprising administering an effective amount of [emtricitabine], or its physiologically acceptable salt, optionally in a pharmaceutically acceptable carrier." On information and belief, Aurobindo will infringe Claim 1 of the '245 Patent because the product for which it seeks approval in ANDA No. 21-1640 will be labeled for and used to treat HIV infection in humans with an effective amount of emtricitabine. For the same reasons, on information and belief, Aurobindo will likewise infringe Claims 2, 4, 6, 7 and 8 of the '245 Patent.

ANSWER: Denied.

40. On information and belief, the tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, will be administered to human patients in an effective amount for treating HIV infection. Such administration will infringe at least one claim of the '245 Patent, as described in the preceding paragraph. On information and belief, this administration will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '245 Patent. Further, by filing ANDA No. 21-1640 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '245 Patent.

ANSWER: Denied.

COUNT 2
Infringement of U.S. Patent No. 6,703,396

41. Plaintiffs repeat and reallege paragraphs 1-29 above as if set forth herein.

ANSWER: Aurobindo repeat, reiterate and re-allege their responses to paragraph 1 through and including 40 of the Complaint with the same force and effect as if hereinafter set forth at length.

42. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of

emtricitabine/tenofovir disoproxil fumarate (i.e., 100mg/150mg, 133mg/200mg, and 167mg/250mg) for the purpose of treating HIV infection.

ANSWER: Admitted.

43. In its April 5, 2018 Notice Letter, Aurobindo USA notified Plaintiffs that it had submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the '396 Patent.[2] This complaint has been filed within 45 days of Plaintiffs' receipt of the April 5, 2018 Notice Letter.

ANSWER: Aurobindo admits that by letter dated April 5, 2018, Aurobindo USA notified Plaintiffs that it had submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the '396 Patent. As Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegation of Paragraph 43 as to the actual receipt date by Plaintiff' of the Notice Letter, it therefore denies the remaining allegations.

44. In its April 5, 2018 Notice Letter, Aurobindo USA notified Plaintiffs that, as a part of its ANDA No. 21-1640, it had filed a Paragraph IV certification with respect to the '396 Patent. Paragraph IV requires, *inter alia,* certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '396 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.

ANSWER: Paragraph 44 contains conclusions of law to which no answer is required. To the extent an answer is required, such allegations are admitted

45. Aurobindo USA alleged in its amended May 9, 2018 Notice Letter that claims 1-7, 11, 13, 15, and 17 of the '396 Patent are invalid and that claims 8-10, 12, 14, 16, and 18-28 would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 21-1640.

[2]Aurobindo amended its Paragraph IV Notice Letter on May 9, 2018.

ANSWER: Plaintiffs are directed to the Notice Letter of May 9, 2018 as the best evidence of what was alleged by Aurobindo

46. The May 9, 2018 Notice Letter does not allege non-infringement of claims 1-7, 11, 13, 15 and 17 of the '396 Patent.

ANSWER: Plaintiffs are directed to the Notice Letter of May 9, 2018 as the best evidence of what was alleged by Aurobindo

47. By filing ANDA No. 21-1640 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate before the '396 Patent's expiration, Aurobindo has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

48. Aurobindo's submission of ANDA No. 21-1640 and service of the April 5, 2018 Notice Letter indicates a refusal to change its current course of action.

ANSWER: Denied.

49. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, will infringe one or more claims of the '396 Patent.

ANSWER: Denied.

50. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 2 of the '396 Patent. Claim 2 recites "[emtricitabine] or a pharmaceutically acceptable salt, ester or salt of an ester thereof." On information and belief, Aurobindo will infringe Claim 2 of the '396 Patent because the product for which it seeks approval in ANDA No. 21-1640 will contain emtricitabine as the active ingredient. For the same reasons, on information and belief, Aurobindo will also infringe Claims 1, 3-7, 13, 15 and 16 of the '396 Patent.

ANSWER: Denied.

51. On information and belief, the tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in

ANDA No. 21-1640, if approved, will infringe at least one claim of the '396 Patent, as described in the preceding paragraph. On information and belief, the manufacture of these tablets will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet the manufacture of these tablets with knowledge that it is in contravention of Plaintiffs' rights under the '396 Patent. Further, by filing ANDA No. 21-1640 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '396 Patent.

ANSWER: Denied.

PLAINTIFFS' PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) **A judgment declaring that the effective date of any approval of Aurobindo's ANDA No. 21-1640 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '245 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;**

(b) **A judgment declaring that the effective date of any approval of Aurobindo's ANDA No. 21-1640 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '396 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;**

(c) **A judgment declaring that the '245 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;**

(d) **A judgment declaring that the '396 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;**

(e) **A permanent injunction against any infringement of the '245 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;**

(f) **A permanent injunction against any infringement of the '396 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;**

(g) **To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the '245 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;**

(h) **To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the '396 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;**

(i) **Costs and expenses in this action; and**

(j) **Such other relief as this Court may deem proper.**

ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF: Aurobindo denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief, inclusive of subparagraphs (a) – (j).

ADDITIONAL DEFENSES

DEFENDANTS assert the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE (INVALIDITY AND UNENFORCEABILITY)

The '245 and '396 Patents, and each of the claims thereof, are invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability as detailed in Aurobindo's Notice Letter (Detailed Statement).

THIRD AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)

As detailed in Aurobindo's Notice Letter (Detailed Statement) Aurobindo does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '245 and '396 Patents; and Aurobindo's products that are the subject of ANDA No. 21-1640 do not infringe any valid and enforceable claim of the '245 and '396 Patents.

FOURTH AFFIRMATIVE DEFENSE
(NO INFRINGEMENT BY INDUCEMENT OR CONTRIBUTORY ACTIONS)

DEFENDANTS have not, do not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '245 and '396 Patents, and the manufacturing, marketing sale, offer for sale, importation, and/or distribution of the product described in ANDA. No. 21-1640 do not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '245 and '396 Patents.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs fail to state a proper claim for willful infringement or exceptional case under 35 §§ 271(e)(4) and 285, or otherwise.

SEVENTH AFFIRMATIVE DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

AUROBINDO'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Aurobindo Pharmaceuticals, USA Inc. and Aurobindo Pharma Ltd. ("Aurobindo"), by way of its attorneys, hereby states for its Counterclaims against Gilead Sciences, Inc. and Emory University (collectively, "Counterclaim Defendants"), the following:

1. Aurobindo repeats and incorporates by reference each of the foregoing paragraphs of Aurobindo's Answer and Additional Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent Nos. 6,642,245 (the "'245 Patent") and 6,703,396 (the "'396 Patent"). Upon information and belief, a true and correct copy of the '245 and '396 Patents were attached to the Complaint as Exhibit A.

THE PARTIES

3. Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad—500 038, Andhra Pradesh, India. Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 279, Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA. Collectively and individually such Aurobindo companies are referenced as "Aurobindo" herein.

4. On information and belief, based on this complaint filed in Civil Action No. 1:18-cv-00765-JFB-SRF (D.Del) against Aurobindo, Gilead Sciences, Inc. ("Gilead") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business

at 333 Lakeside Drive, Foster City, California 94404.

5. On information and belief, based on this complaint filed in Civil Action No. 1:18-cv-00765-JFB-SRF (D.Del) against Aurobindo, Emory University ("Emory") is non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

6. Collectively, Gilead and Emory are referenced herein as "Counterclaim-Defendants."

JURISDICTION

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Aurobindo, on the one hand, and the Counterclaim-Defendants on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This Court has personal jurisdiction over Counterclaim-Defendants based, *inter alia,* on the filing by Counterclaim-Defendants of this lawsuit, Civil Action No. 1:18-cv-00765-JFB-SRF (D.Del), against Aurobindo, in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ORANGE BOOK LISTING OF THE '245 AND '396 PATENT

9. On information and belief, on November 4, 2003, the United States Patent and Trademark Office issued the '245 Patent, entitled "Anitviral Activity and Resolution of 2-Hydroxymethyl—5-(5-fluorocytosin-1-yl)-1,3-oxathiolane." United States Patent and

Trademark Assignment records indicate that the '245 Patent is assigned to Emory.

10. On information and belief, on March 9, 2004, 2003, the United States Patent and Trademark Office issued the '396 Patent, entitled "Method of Resolution and Anitviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers." United States Patent and Trademark Assignment records indicate that the '396Patent is assigned to Emory

11. According to the Complaint in this case, pursuant to an agreement entered into between Gilead and Emory, Gilead has substantial rights in the '245 and '396 Patents, including, but not limited to, rights associated with being a licensee of the '245 and '396 Patents, and the right to sue for infringement of the '245 and '396 Patents..

12. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patent s covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

13. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), Counterclaim-Defendants caused the FDA to list the '245 and '396 Patent in the Orange Book in connection with NDA No. 21-752 for Truvada®, emtricitabine and tenofovir disoproxil fumarate ("the Truvada® NDA").

14. By maintaining the listings of the '245 and '396 Patents in the Orange Book, Counterclaim-Defendants represent to the world that the '245 and '396 Patents could reasonably be asserted if a person not licensed by the owner [of the '245 and '396 Patents] engaged in the manufacture, use, or sale" (21 U .S.C. § 355(b)(l)) of emtricitabine and tenofovir disoproxil fumarate oral tablets, before the expiration of the '245 and '396 Patents.

AUROBINDO'S ABBREVIATED NEW DRUG APPLICATION

15. Aurobindo filed ANDA No. 21-1640 with the FDA seeking approval to market emtricitabine and tenofovir disoproxil fumarate oral tablets containing 100mg/150 mg, 133 mg/200mg and 167 mg/250mg for the use for which Aurobindo seeks approval in ANDA No. 21-1640 ("low dose strengths").

16. By letter of April 5, 2018, Plaintiffs were notified of the filing of Aurobindo's ANDA No. 21-1640 with respect to low dose strengths, and that Aurobindo is seeking approval to market emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths, prior to the expiration of the '245 and '396 Patents, that the ANDA contained a Paragraph IV Certification to the '245 and '396 Patents, and of Aurobindo's factual and legal bases ("Detailed Statement") for asserting that '245 and '396 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in the ANDA.

THE PRESENCE OF A CASE OR CONTROVERSY

17. By maintaining the Orange Book listing of the '245 and '396 Patents in connection with the Truvada® NDA, Counterclaim Defendants continue to represent that the '245 and '396 Patents could reasonably be asserted against anyone making, using or selling generic emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths without a license from the Counterclaim Defendants prior to the expiration of the '245 and '396 Patents.

18. Counterclaim-Defendants have filed an infringement action under 35 U.S.C. §

271(e)(2)(A) and 35 U.S.C. §§ 271(a), (b), and (c) asserting the '245 and '396 Patents against Aurobindo. There has been, and is now, an actual and justiciable controversy between Aurobindo on the one hand, and Counterclaim-Defendants, on the other hand as to whether the products disclosed in Aurobindo's ANDA No. 21-1640 infringe the '245 and '396 Patents and whether any valid, enforceable claim in the '245 and '396 Patents exists.

19. Aurobindo seeks to market emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths that is the subject of ANDA No. 21-1640 in the United States prior to the expiration of the '245 and '396 Patents.

20. If Aurobindo succeeds in proving that its emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths do not infringe the '245 and '396 Patents, or that the '245 and '396 Patents are invalid or unenforceable, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim-Defendants' maintenance of the '245 and '396 Patents in the Orange Book in connection with the Truvada® NDA.

21. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendants and Aurobindo as to whether the claims of the '245 and '396 Patents are invalid and/or not infringed by Aurobindo.

COUNT I

(Declaratory Judgment Of Non-Infringement Of The '245 And '396 Patents)

22. Aurobindo repeats and incorporates by reference Paragraphs 1-21 of Aurobindo's Counterclaims, above, as if fully set forth herein.

23. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Aurobindo and Counterclaim-Defendants concerning the claims of the '245 and '396 Patents.

24. Counterclaim-Defendants allege that the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths described in ANDA No. 21-1640infringes the claims of the '245 and '396 Patents.

25. Aurobindo asserts that no valid claim of the '245 and '396 Patents is infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths described in ANDA No. 21-1640

26. Aurobindo is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths described in ANDA No. 21-1640, does not infringe any valid claim of the '245 and '396 Patents.

COUNT II

(Declaratory Judgment Of Invalidity Of The '245 And '396 Patents)

27. Aurobindo repeats and incorporates by reference Paragraph s 1-26 of Aurobindo's Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

28. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.,* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Aurobindo and Counterclaim-Defendants concerning the claims of the '245 and '396 Patents.

29. Counterclaim-Defendants allege that the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo 's emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths described in ANDA No. 21-1640, infringes the claims of the '245 and '396 Patents.

30. Aurobindo asserts that the manufacture, use, offer-for-sale, sale, and/or importation of Aurobindo's emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths described in ANDA No.21-1640 does not infringe any valid claim of the '245 and '396 Patents, and that the claims of the '245 and '396 Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

31. Aurobindo is entitled to a declaration that the claims of the '245 and '396 Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully requests that the Court enter judgement in its favor and against Plaintiffs and Counterclaim-Defendants as follows:

A. For a declaration that the claims of U.S. Patent Nos. 6,642,245 (the "'245 Patent") and 6,703,396 (the "'396 Patent") are invalid;

B. For a declaration that the claims of U.S. Patent Nos. 6,642,245 (the "'245 Patent") and 6,703,396 (the "'396 Patent") are not and will not be infringed by Aurobindo's manufacture, use, sale, offer for sale, or importation of emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths described in ANDA No. 21-1640;

C. Preliminarily and permanently enjoining Plaintiffs/Counter-Defendants, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from utilizing 6,642,245 (the "'245 Patent") and 6,703,396 (the "'396 Patent") to block, hamper, hinder or obstruct FDA approval of Aurobindo's proposed emtricitabine and tenofovir disoproxil fumarate oral tablets in low dose strengths;

D. Permanently enjoining Plaintiffs/Counter-Defendants, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from asserting or otherwise seeking to enforce U.S. Patent No. 6,642,245 (the "'245 Patent") and 6,703,396 (the "'396 Patent") against Aurobindo or anyone in privity with Aurobindo;

E. Granting Aurobindo judgment in its favor on Plaintiffs' Complaint;

F. Denying any request by Plaintiffs for relief requested in their complaint;

G. Dismissing Plaintiffs' Complaint with prejudice;

H. Declaring this case exceptional and awarding Aurobindo its attorneys' fees pursuant to 35 U.S.C. § 285, the inherent power of this court, or otherwise;

I. Awarding costs to Aurobindo; and

J. Awarding any other such and further relief as is just and proper.

Dated: September 12, 2018

CONNOLLY GALLAGHER LLP

/s/ *Arthur G. Connolly, III*

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